

REMARKS

The claims have been amended to more precisely define the invention. In particular, claims 1-3, 8-9, 15-16 and 21-22 have been amended, claims 7, 12 and 23-24 have been cancelled and new claim 25 has been added to the application. In keeping with the Examiner's suggestion, the description of the priority claim has been amended to specify that the PCT Publication was in English. In view of the nature of these amendments, it is submitted that no new matter has been added to the application.

Claims 1-7, 9-10, 12 and 15-24 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is traversed and it is submitted that the claims now in the application are in full compliance with the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, reconsideration and withdrawal of the rejection are requested.

In support of the rejection, the Examiner alleged that the phrases "mammalian-type sugar chain" and "human-type sugar chain" are indefinite. In view of the deletion of these phrases from the claims, it is submitted that this aspect of the rejection is no longer applicable to the claims now in the application. Accordingly, reconsideration and withdrawal of this aspect of the rejection are requested.

In further support of the rejection, the Examiner further took the position that the absence of method steps in the claims to produce a "mammalian-type or human-type sugar chain" without xylose or fucose renders the claims indefinite. In view of the cancellation of claims 7 and 12 and the deletion of this phrase from claim 15, it is submitted that this aspect of the rejection is no longer applicable to the claims now in

the application. Accordingly, reconsideration and withdrawal of this aspect of the rejection are requested.

In further support of the rejection, the Examiner alleged that claim 8 is indefinite because “it is unclear what the plant is transformed with, [and] it is unclear if the plant cell inherently compris[es] a sugar chain adding mechanism or if such mechanism is introduced.” In view of the amendment to claim 8, it is submitted that this rejection is no longer applicable. Accordingly, reconsideration and withdrawal of this aspect of the rejection are requested.

In further support of the rejection, the Examiner alleged that claim 9 is indefinite in the recitation of the phrase “which can improve the performance of the first enzyme” and claim 10 is indefinite because “it is unclear how the listed ‘second enzyme’ improve[s] the performance of the first enzyme.” In view of the deletion of this phrase from dependent claim 9, it is submitted that this aspect of the rejection is no longer applicable to the claims now in the application. Accordingly, reconsideration and withdrawal of this aspect of the rejection are requested.

In further support of the rejection, the Examiner alleges that claim 15 is indefinite because the phrase “a gene encoding an exogenous glycoprotein” is not commensurate with the phrase “selected from one or more of.” In view of the amendment made to the phrase “selected from one or more of” in claim 15, it is submitted that this aspect of the rejection is no longer applicable to the claims now in the application. Accordingly, reconsideration and withdrawal of this aspect of the rejection are requested.

In further support of the rejection, the Examiner alleged that claim 16 is indefinite in the recitation of the phrase “capable of enhancing the efficiency of the glycosyl transferase enzyme.” In view of the deletion of this phrase from dependent

claim 16, it is submitted that this aspect of the rejection is no longer applicable to the claims now in the application. Also, deletion of this phrase appears to remedy the Examiner's issue with respect to dependent claim 17. Accordingly, reconsideration and withdrawal of these aspects of the rejection are requested.

In further support of the rejection, the Examiner alleged that claims the phrase "the exogenous glycoprotein" lacks proper antecedent basis in independent claim 15. The Examiner's attention is directed to independent claim 15, where the phrase "an exogenous glycoprotein" is contained therein. Accordingly, reconsideration and withdrawal of this aspect of the rejection is requested.

In further support of the rejection, the Examiner alleged that the phrase "derived from" renders claims 21-22 indefinite. In keeping with the Examiner's suggestion, the term "derived" has been deleted from these claims. Accordingly, reconsideration and withdrawal of the rejection are requested.

In further support of the rejection, the Examiner alleged that claim 22 uses an improper Markush format. In keeping with the Examiner's suggestion, the conjunction "or" in line 3 has been changed to "and." Accordingly, reconsideration and withdrawal of the rejection are requested.

In support of the rejection, the Examiner also took the position that claims 4-7 were indefinite because there are no positive method steps recited in the claims that produce the claimed structure. This rejection is traversed and it is submitted that claims 4-6 (claim 7 has been cancelled) are in full compliance with the requirements of 35 U.S.C. § 112, second paragraph.

It is well-settled that the Examiner is charged with the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention under the second paragraph of 35 U.S.C. §112, for indefiniteness, and that this burden is not

discharged merely because the claim language does not meet the Examiner's own preference. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971); *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1973). Rather, the Examiner is obliged to provide a basis to support the determination that one having ordinary skill in the art would not have understood what is claimed when the claim is read in light of the specification. *Morton International, Inc. v. Cardinal Chemical Co.*, 5 F.3d 1464, 28 USPQ2d 1190 (Fed. Cir. 1993); *In re Warmerdam*, 33 F.3d 1354, 31 USPQ2d 1754 (Fed. Cir. 1994); *Process Control Corp. v. Hydrex Corp.*, 190 F.3d 1350, 52 USPQ2d 1029 (Fed. Cir. 1999).

With respect to the Examiner's allegations concerning claims 4-6, it is submitted that the Examiner failed to provide any logical basis to support the conclusion that one having ordinary skill in the art would not have understood what is claimed when read in light of the specification. The recitation of further method steps in the claims is not a prerequisite to understanding what is meant by the claims. It is the function of the claims to define the limits of the invention, and it is the function of the specification to detail how the invention is to be practiced and to set forth the practical limits of operation of the invention. *In re Roberts*, 470 F.2d 1399, 176 USPQ 313 (CCPA 1973); *In re Johnson* 558 F.2d 1008, 194 USPQ 187 (CCPA 1977); *In re Rainer*, 305 F.2d 505, 134 USPQ 343 (CCPA 1962). Thus, one does not look to the claims to find out how to practice the invention they define, but to the specification. *In re Roberts, supra.*; *In re Fuetterer*, 319 F.2d 259, 138 USPQ 217 (CCPA 1963). Accordingly, it is submitted that this aspect of the rejection is improper and accordingly, reconsideration and withdrawal of this aspect of the rejection under 35 U.S.C. § 112, second paragraph are requested.

Claims 1-12 and 15-24 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In support of the rejection, the Examiner alleges that “[t]he claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is traversed and it is submitted that the claims now in the application are in full compliance with the written description requirements of 35 U.S.C. § 112, first paragraph. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph are requested.

Claims 1-12 and 15-24 were rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. In support of the rejection, the Examiner alleges that “the specification, while being enabling for a method of manufacturing a glycoprotein in a transgenic plant having terminal galactose residues in the N-glycosylation portion of a glycoprotein comprising transforming said plant with a transgene encoding a mammalian β 1,4-galactosyltransferase, and a plant transformed therewith which also comprises a transgene encoding an exogenous glycoprotein, does not reasonably provide enablement for a method of manufacturing a glycoprotein having a human-type sugar chain comprising transforming a plant cell with any gene encoding a glycosyltransferase.” This rejection is traversed and it is submitted that the amended claims now in the application are in full compliance with the enablement requirements of 35 U.S.C. § 112, first paragraph. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph are requested.

Claims 1-7 and 23-24 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,602,684 to Umana. This rejection is traversed and it

is submitted that the claims are in full compliance with the requirements of 35 U.S.C. § 102(e).

It is well-settled that a patent applicant may antedate subject matter in a U.S. Patent, provided that the same invention is not claimed in the U.S. Patent, by establishing a pre-filing date of invention earlier than the effective filing date of the U.S. Patent. 37 C.F.R. § 1.131; *In re Zletz*, 13 USPQ 1320, 1322-23 (Fed. Cir. 1989). The purpose of a Rule 131 declaration is to overcome a prior art rejection by establishing that the applicants invented claimed subject matter before the effective filing date of the prior art reference. *M.P.E.P.* 715.01.

In this regard, the Examiner's attention is directed to the enclosed Rule 131 Declaration establishing that Tatsuji Seki and Kazuhito Fujiyama reduced to practice the subject matter of independent claim 1 before April 20, 1998, i.e., the effective filing date of the Umana patent. Accordingly, it is submitted that this rejection is no longer applicable and reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(e) are requested.

Claims 8-12 and 15-22 were rejected under 35 U.S.C. § 103 as being unpatentable over Umana in view of U.S. Patent No. 5,959,177 to Hein. This rejection is traversed and it is submitted that in view of the enclosed Rule 131 Declaration discussed above, claims 8-12 and 15-22 are in full compliance with the requirements of 35 U.S.C. § 103. Accordingly, it is submitted that this rejection is no longer applicable and reconsideration and withdrawal of the rejection under 35 U.S.C. § 103 are requested.

Claims 1-12 and 15-24 were rejected under 35 U.S.C. § 103 as being unpatentable over Zhang in view of Umana and Hein. This rejection is traversed and

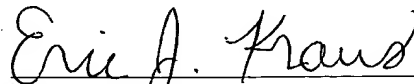
it is submitted that the claims are in full compliance with the requirements of 35 U.S.C. § 103.

It is well-settled that an inventor may overcome a prior art rejection by establishing that an applied prior art publication describes the inventor's own work. 37 C.F.R. § 1.132; *In re Katz*, 215 U.S.P.Q. 14 (C.C.P.A. 1982). In this regard, the Examiner's attention is directed to the enclosed Rule 132 Declaration establishing that the publication "Transformation of Tobacco Using Human β -1,4-galactosyltransferase Gene and Regeneration of Transgenic Plants" Annual Reports of IC Biotech, p. 241-247, Vol. 18, 1995, publicly available August 31, 1998 discloses the two joint inventors' own work. Accordingly, it is submitted that this rejection is no longer applicable and reconsideration and withdrawal of the rejection under 35 U.S.C. § 103 are requested.

In view of the amendments and remarks presented with this response, it is urged that the rejections of record are overcome and the present application is in condition for allowance. Favorable consideration of this application is requested.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 04-1512 and please credit any excess fees to such deposit account.

Respectfully submitted,



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